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APR 1 0 2001

Special 510(k)
Nucletron PLATO SRS
23 Februari 2001

Nucletron

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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Robert Applebaum, C.H.P., R.S.O. Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	PLATO SRS Stereotactic Radiosurgery planning System V2
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accessory to Accelerator, Linear, Medical
Classification	21 CFR 892.5050 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate devices cited in the table below:

Manufacturer	Device	510(k) #
Nucletron	PLATO SRS Stereotactic Radiosurgery planning System	K940001
ADAC Laboratories	Pinacle^3	K993923
Nucletron	PLATO RTS-2 3D Radiation Treatment Planning System	K964206

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Description:

The PLATO SRS Stereotactic Radiosurgery planning System is a set of software modules that are installed and run on the PLATO radiation therapy treatment planning system. PLATO SRS modules provides the capability to produce treatment plans for stereotactic radiosurgery.

Treatment planning for Radiosurgery makes use of features and has characteristics that are specific to the treatment technique:

- small, circular radiation beams
- non-coplanar arcs intersecting at the target volume
- stereotactic frame localisation

Modifications to PLATO SRS and related modules, previously cleared under K940001, have been made to add functionality for:

- the correlation and display of images from different imaging modalities such as CT and MR
- the transfer of user – defined contours from images of one modality to another, for subsequent use in treatment planning on the PLATO radiation therapy planning system.

Jointly referred to as "image fusion" and

- Other changes that improve the ease of use of the software

The intended use is: Treatment of Cancer

The indications for use are:

PLATO SRS Stereotactic Radiosurgery planning System V2 is an accessory to medical linear accelerators used for radiation therapy. It is used for 3 dimensional planning of radiation therapy.

Summary of technological considerations:

The Nucletron PLATO SRS Stereotactic Radiosurgery planning System V2 is substantially equivalent to the cleared predicate device, PLATO SRS Stereotactic Radiosurgery planning System (K940001)

T.J. Bateman

Name: T.J. Bateman
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

Feb 21 2001

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2001

Robert Applebaum, C.H.P., R.S.O.
Director Assurance & Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K010784
Plato SRS Stereotactic Radiosurgery
Planning System V2.0
Dated: March 15, 2001
Received: March 15, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 MUJ

Dear Mr. Applebaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Nucletron

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Statement of intended use

Device Name: PLATO SRS Stereotactic Radiosurgery planning System

Intended use: Treatment of Cancer

The indications for use are:

PLATO SRS Stereotactic Radiosurgery planning System V2 is an accessory to medical linear accelerators used for radiation therapy. It is used for 3 dimensional planning of radiation therapy.

Prescription use:
The Nucletron PLATO SRS Stereotactic Radiosurgery planning System is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

T J Bt

Name: T.J. Bateman
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

Feb 21 2001

Date

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010784

Prescription Use ✓
(Per 21 CFR 801.109)